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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,305	12/06/2001	Charles E. Prussak	ST-UCSD3140	1335

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EXAMINER	
GAMBEL, PHILLIP	
ART UNIT	PAPER NUMBER
1644	

MAIL DATE	DELIVERY MODE
11/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/006,305	PRUSSAK ET AL.	
	Examiner	Art Unit	
	Phillip Gambel	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4,8,11,12,14,16-21,23-29,32-41,43-51,62-68 and 76-79* is/are pending in the application.

4a) Of the above claim(s) *14, 16-21, 23-26, 43-51 and 62-67* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4,8,11,12,27-29,32-41,68 and 76-79* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/28/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed 07/31/2009, has been entered.

Claims 2-4, 11 and 76 have been amended.

Claims 1, 5-7, 9-10, 13, 15, 22, 30-31, 42, 52-61 and 69-75 have been canceled previously

Claims 2-4, 8, 11-12, 14, 16-21, 23-29, 32-41, 43-51, 62-68 and 76-79 are pending.

Claims 2-4, 8, 11-12, 27-29, 32-41, 68 and 76-79 are being acted upon as the elected invention.

As noted previously, applicant's election without traverse of Group I for examination, and the species wherein Domains I, II and III are fragments of CD154 (i.e. CD40L), while Domain IV comprised a fragment of human TNFα has been acknowledged.

Also, as indicated previously,
for examination purposes, the elected claims 2-4, 8, 11-12, 27-29, 32-41 and 68-75 are being examined to the extent they read on the elected species wherein Domains I, II and III are fragments of CD154 (i.e. CD40L), while Domain IV comprised a fragment of human TNFα.

Claims 14, 16-21, 23-26, 43-51 and 62-67 have been withdrawn from consideration as being drawn to the nonelected inventions and/or species.

2. The text of those sections of Title 35 USC not included in this Action can be found in a prior Office Action.

This Action will be in response to applicant's arguments, filed 07/31/2009.

The rejections of record can be found in previous Office Action, mailed 03/31/2009.

3. Upon reconsideration of applicant's arguments based upon the written description in the specification and amended claims, filed 07/31/2009; the previous rejection under 35 U.S.C. § 112, first paragraph, written description/new matter, with respect to the recitation of "the Domain III comprises a CD154 fragment lacking a metalloproteinase cleavage site present in wild-type CD154" has been withdrawn.

4. Upon reconsideration of applicant's arguments based upon the written description in the specification and amended claims, filed 07/31/2009; the previous rejection under 35 U.S.C. § 112, first paragraph, written description/new matter, with respect to the recitation of "a CD154 fragment lacking a metalloproteinase cleavage site present in wild-type CD154" has been withdrawn.

5. This is a 35 U.S.C § 112, first paragraph, "written description" (and not new matter).

Claims 2-4, 8, 11-12, 27-29, 32-41, 68 and 76-79 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed.

The specification as originally filed does not provide support for the invention as now claimed:
"than are native TNFα and TNFα lacking a mmp cleavage site between Val77 and Pro88 of native TNFα".

Applicant's arguments, filed 07/31/2009, have been fully considered but have not been found convincing essentially for the reasons of record.

While applicant directs support to the specification, particularly paragraphs [0078] and [0082], as well as submitting that the rate of soluble TNFα production from native TNFα is known in the art and described in the specification;
There is insufficient written description of the reference sequence (e.g. SEQ ID NO.) and, in turn, there is insufficient description of "a mmp cleavage site between Val77 and Pro88 of native TNFα".

The following of record is reiterated for applicant's convenience.

With respect to the recitation of "than are native TNFα and TNFα lacking a mmp cleavage site between Val77 and Pro88 of native TNFα",
the specification does not appear to provide a clear description of necessary functional characteristics coupled with a known or disclosed correlation between function and structure of native TNFα.
There is insufficient written description as to whether the recitation of "native TNFα" describes a particular species of native TNFα (e.g., human, mouse), TNFα before or after processing or transmembrane or soluble TNFα.
Further, in the absence of a reference sequence (e.g. SEQ ID NO.), there is insufficient description of "a mmp cleavage site between Val77 and Pro88 of native TNFα".

For example, Attwood (Science 2000; 290:471-473) teaches that "[i]t is presumptuous to make functional assignments merely on the basis of some degree of similarity between sequences.

Skolnick et al. (Trends in Biotech., 18(1):34-39, 2000) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2).

Applicant was not in possession of the claimed genera of "CD154 fragments" or "native TNFα" as elements of the claimed nucleic acid molecules in the absence of providing sufficient structural and functional characteristics of the genera of such "CD154 fragments" or "native TNFα" encompassed by the instant claim language, coupled with a known or disclosed correlation between function and structure.

The instant application has not provided a sufficient description showing possession of the necessary functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genera of "CD154 fragments" or "native TNFα" broadly encompassed by the claimed invention.

Further, the Court has interpreted 35 U.S.C. §112, first paragraph, to require the patent specification to "describe the claimed invention so that one skilled in the art can recognize what is claimed. Enzo Biochem, Inc. v. Gen-Probe Inc, 63 USPQ2d 1609 and 1618 (Fed. Cir. 2002). In evaluating whether a patentee has fulfilled this requirement, our standard is that the patent's "disclosure must allow one skilled in the art 'to visualize or recognize the identity of' the subject matter purportedly described." Id. (quoting Regents of Univ. of Cal. v. Eli Lilly & Co., 43 USPQ2d 1398 (Fed Cir. 1997)).

The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus.

It is not sufficient to define a genus without sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics.

In the absence of sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, the claimed invention is not described in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.). Consequently, Applicant was not in possession of the instant claimed invention. See University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

The problem here is that the instant specification fails to provide a disclosure of which "CD154 fragments" or "native TNFα molecules" are required for the claimed nucleic acid molecules, broadly encompassed by the claimed invention.

A skilled artisan cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus that exhibit this functional property.

Therefore, there is insufficient written description for genera of "B7 antigens", broadly encompassed by the claimed invention at the time the invention was made and as disclosed in the specification as filed under the written description provision of 35 USC 112, first paragraph.

Applicant has been reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicant is reminded that the amendment must point to a basis in the specification so as not to add any new matter. See MPEP 714.02 and 2163.06.

Alternatively, applicant is invited to consider the following with respect to providing the reference sequence essential to the claimed invention, including a possible reliance upon Mueller et al, J. Biol. Chem. 273: 38112-38118, 1999 (described in paragraph [0082] of the specification; also see 1449 of record).

The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See In re Hawkins, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); In re Hawkins, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and In re Hawkins, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

An application as filed must be complete in itself in order to comply with 35 U.S.C. 112; however this does not bar incorporation by reference. Ex parte Schwarze, 151 USPQ 426 (Bd. of Appeals, 1966). an application for a patent when filed may incorporate "essential material" by reference to (1) a United States patent or (2) an allowed U.S. application, subject to the conditions set forth below. "Essential material" is defined as that which is necessary to (1) support the claims, or (2) for adequate disclosure of the invention (35 U.S.C. 112). "Essential material" may not be incorporated by reference to (1) patents or applications published by foreign countries or regional patent offices, to (2) non-patent publications, to (3) a U.S. patent or application which itself incorporates "essential material" by reference or to (4) a foreign application. See In re Fouche, 169 USPQ 429; 439 F.2d 1237 (CCPA 1971).

Given that the amino acid sequence of the cleavage site or the referenced TNFα is considered essential subject matter to the instant application and the claimed invention.

Applicant is reminded to provide said Sequence Listing which complies with the requirements of 37 CFR 1.821 through 1.825 for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

Also, applicant is reminded to provide the appropriate Hawkins Declaration to accompany amending the instant specification to provide the essential subject of the amino acid sequence defining the claimed cleavage site or the referenced TNFα.

If applicant intends to pursue incorporation by reference, applicant should contact the examiner to verify written support in the specification as filed.

6. Claims 2-4, 8, 11-12, 27-29, 32-41, 68 and 76-79 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention

It is apparent that the HeLa, 293, A549, COLO205, HCT-15, BT-20 and HT1080 cells / cell lines are required to practice the claimed invention. As required elements, they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it is not so obtainable or available, the enablement requirements of 35 USC 112, first paragraph, may be satisfied by a deposit of the cell lines. See 37 CFR 1.801-1.809.

In addition to the conditions under the Budapest Treaty, applicant is required to satisfy that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent in U.S. patent applications.

Amendment of the specification to recite the date of deposit and the complete name and address of the depository is required. As an additional means for completing the record, applicant may submit a copy of the contract with the depository for deposit and maintenance of each deposit.

Alternatively, applicant is invited to clarify that the claimed HeLa, 293, A549, COLO205, HCT-15, BT-20 and HT1080 cells / cell lines were known and readily available to the public.

Biological materials must be known and readily available to the public (See MPEP 2404.01). Neither concept alone is sufficient. The fact that applicant and other members of the public were able to obtain the materials in question from a given depository prior to and after the filing date of the application does not establish the upon issuance of a patent on the application that such material would continue to be accessible to the public. The applicant did not make of record any of the facts and circumstances surrounding the access to the biological materials from a depository, nor is there any evidence as to the depository's policy regarding the material if a patent would be granted. Further, there is no assurance that the depository would allow unlimited access to the material if the application has matured into a patent.

In the absence of evidence that the claimed HeLa, 293, A549, COLO205, HCT-15, BT-20 and HT1080 cell lines were readily available to the public and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent.

Further, it is noted that the recitation of "HCT-15" and "BT-20" is not consistent with the designation of these cell lines in the specification as filed (e.g., see paragraph [0111], "HCT15" and "BT20").

7. Upon reconsideration of applicant's arguments and amendments, filed 07/31/2009, the previous rejection under 35 U.S.C. §. 103(a) as being unpatentable over Kipps et al. (U.S. Patent No. 7,070,771) AND/OR Kipps et al. (WO 98/26061) in view of Mueller et al. (J. Biol. Chem.274: 1999) (1449) and Kornbluth (US 2005/0158831 A1) has been withdrawn.

8. The terminal disclaimers filed on 07/31/2009, disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent Nos. 7,495,090; 7,071,771 and 7,542,944 (USSN 11/015,117 cited in the previous Office Action) have been reviewed and have been accepted. The terminal disclaimers have been recorded.

9. Claims 2-4, 8, 11-12, 27-29, 32-41, 68 and 76-79 are directed to an invention not patentably distinct from
over claims 66 and 68-75 of commonly assigned USSN 11/015,117 and
over claims 1-15 of commonly assigned U.S. Patent No. 7,070,771.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned U.S. Patent No., discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Applicant's amendment, filed 07/31/200, does not address the issue of commonly owned at the time the invention was made.

Applicant is invited to clarify this issue.

10. No claim is allowed.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (571) 272-0844. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735.

The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Phillip Gambel/
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Art Unit 1644
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